

Remarks/Arguments:

Introduction

Claims 50-54 and 55-90 are pending. Claims 68-90 are withdrawn. Claim 50 has been amended to include the limitations of claim 55. Claim 55 has been canceled.

Section 102 Rejections

In paragraph 6 of the Office Action, claims 50-58 and 62-63 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by US 6,491,283 to Newberg (hereinafter “Newberg”). Applicants respectfully traverse.

In response to the objection at paragraph 2, page 3, lines 3 -10, the objected-to recitation of Claim 50 has been clarified as recited below so it is clearly directed to a structural limitation and not a manner in which the claimed apparatus is to be employed.

With regard to the Examiner's opinion expressed at paragraph 2, in the passage bridging pages 2 and 3 of the Office Action that “surface contact would at least cause deformation at a minute level” and that “any two things will deform when pushed together with enough force”, Applicants respectfully disagree. A surface contact between two objects, whether positive or neutral, does not automatically cause deformation, let alone a deformation which involves displacement of material. The presence of counteracting compensated (i.e. action and reaction) forces between two objects merely means that the two objects are in a static equilibrium and not that they necessarily become deformed. Newberg does not provide any teaching as to the details of the contact between the cap 74 and the sealing surface 21, i.e. whether the contact is positive or neutral. Nor does it mention any deformation. Even if it is possible to infer from Newberg that there exists a positive contact between these portions, it is not taught or implied in Newberg that these elements 74, 21 actually deform and that the deformation involves displacement of portions of these two elements.

As Newberg fails to disclose, *inter alia*, materials of a sharp rim and a curved surface area are elastically deforming to seal an opening of a valve, as set forth in claim 50, the Examiner must then properly apply an inherency argument to the missing descriptive matter of Newberg. To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *Crown Oper. Int'l Inc. v. Solutia Inc.*, 289 F.3d 1367, 62 U.S.P.Q.2d 1917 (Fed. Cir. 2002). Further, inherency may not be established by probabilities or possibilities, and the mere fact that a certain thing may result from a given set of circumstances is not sufficient for a *prima facie* case of anticipation. *Scaltech Inc. v. Retec/Tetra L.L.C.*, 153 F.3d 1193, 51 U.S.P.Q.2d 1055 (Fed. Cir. 1999). Occasional results are not inherent. *Mehl/Biophile Int'l Corp. v. Milgram*, 192 F.3d 1365, 52 U.S.P.Q.2d 1303, 1306 (Fed. Cir. 1999). Clearly, the disclosure of Newberg does not rise to the level of being an anticipatory prior art reference

Moreover, all claim limitations and claim words must be considered by the Examiner. (*In re Wilson*, 424 F.2d 1382, 1.85, 165 USPQ 4945, 496 (CCPA 1970), MPEP (8th Ed Revised July 2008) §2143.03). It is impermissible during examination to pick and choose from a reference only so much that supports the alleged rejection, and a cited reference must be considered for the entirety of its teachings. *Bausch & Lomb, Inc. v. Barnes-Hind, Inc.*, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986).

Thus, Applicants respectfully maintain that the amended feature of Claim 1, i.e.:

“wherein in the closed position of the valve (1, 121, 700, 800, 400, 900, 990), the sharp rim (15) is engaged with the curved surface area (22) and a portion of the curved surface area (22) is displaced by the sharp rim (15) and wherein the materials of the sharp rim (15) and the curved surface area (22) are elastically deformed to seal the opening of the valve (1, 121, 700, 800, 400, 900, 990)”

is not taught by Newberg, as previously submitted on April 17, 2009, and such a limitation must be properly considered by the Examiner.

In response to the rejection of Claim 50 at paragraph 6, page 4 in view of Newberg, Claim 50 has been amended to include the recited-below features of Claim 55 and an additional feature (shown in *italics* below) based on Figures 2 and 9 of the present application:

“wherein the second plastic portion comprises a wall defining a bore portion (13) having a cross-section converging towards the first end (2) of the valve (1, 121, 700, 800, 400, 900, 990) which in turn leads to a wall defining a bore portion (14) having a substantially uniform cross-section which is located adjacent the first end (2) of the valve, the boundary between the wall defining the converging bore portion (13) and the wall defining the substantially uniform cross-section bore portion (14) defining the sharp rim (15), the first plastic portion having a body portion (19) with a cross-section converging towards the first end (2) of the valve and leading to an end portion (20) with a uniform cross-section, the end portion (20) being adjacent the first end (20) of the valve in use and a transitional surface between the external surface of the body portion (19) and the external surface of the end portion (20) of the first plastic portion defining the curved surface area (22),

wherein each of the wall defining the converging bore portion (13) and the wall defining the substantially uniform cross-section bore portion (14) is non-tangential with respect to any point of the portion of the curved surface area (22) which is displaced by the sharp rim (15)”

In all the Figures 1 to 9 of Newberg, including Figure 3 referred to by the Examiner in relation to Claim 55 at page 6 of the Office action, except Figure 8, the annular sealing surface 21 is tangential to the sealing cap (see for example attached Figure 9 and an enlarged area X of Figure 9, attached hereto). Such a tangential surface contact cannot provide a snug contact between the two portions and form a reliable seal that can withstand the rigors of a sterilization process and maintain its integrity. As shown in an enlarged area X' of Figure 9 (attached hereto), the surfaces 21, 84 which originally form a seal become warped having been subjected to harsh processing conditions such as high temperatures, high pressure, high humidity, electromagnetic radiation etc., and the seal between the surfaces 21, 84 becomes compromised. Because of the tangential contact between the annular surface 21 and sealing surface 84,

relatively large flat surface areas of the surfaces 21, 84 are originally in contact, accordingly, a relatively large amount of warpage occurs which considerably compromises the seal.

Unlike Newberg, the present invention as defined in amended Claim 50 provides a combination of a curved surface area and the sharp rim formed by walls which are non-tangential with respect to any point of the portion of the curved surface area which is displaced by the sharp rim. Such a combination of the curvature of curved surface area and the non-tangentiality of the walls of the sharp rim to the portion of the curved surface area deformed by the sharp rim results in that that only a small sharp portion of the second plastic portion pricks the curved surface area so that the area of contact between the first and second plastic portions is minimized considerably thereby minimizing the compromising effect of warpage on the seal. Furthermore, the combination of the above features of the present invention ensures that the sharp rim pricks rather than abuts the curved surface area which also minimizes the negative impact of any warpage.

In Figure 8, although the flat annular surface 23 is non-tangential to the curved sealing surface 84, the “sharp rim” of the flat surface 23 cannot under any circumstance engage the curved surface 84 since the cap 74 is prevented from moving into any contact with the “sharp rim” when the outer circumference of the cap 74 comes into contact with the flat annular surface 23 (see attached copy of Figure 8).

For the above reasons, it is respectfully submitted that amended Claim 50 is novel having regard to Newberg.

Therefore, reconsideration and withdrawal of the rejection of claims 50-58 and 62-63 are rejected under 35 U.S.C. §102(b) to Newberg is respectfully requested.

Section 103 Rejections

A.) In paragraph 9 of the Office Action, claims 61 and 64-66 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Newberg in view of US 6,237,639 to Jougla et al (hereinafter "Jougla"). Applicants respectfully traverse.

As described above, Newberg fails to disclose, teach or suggest the subject matter of independent claim 50. Jougla is cited by the examiner for certain alleged teachings regarding means for displaying to a user the actuation state of a valve, etc.

Jougla, however, fails to cure the deficiencies of Newberg. Accordingly, claims 61 and 64-66 are patentably distinct over Newberg and Jougla.

Reconsideration and withdrawal of the rejection of claims 61 and 64-66 are patentably distinct over Newberg and Jougla.

B.) In paragraph 10 of the Office Action, claims 50 and 59-65 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over WO 03/090842 to Liepold et al (hereinafter "Liepold") in view of US 2002/0074532 to Rovira et al. (hereinafter "Rovira"). Applicants respectfully traverse.

It is unclear why the Examiner cites Liepold for obviousness, since the inventors, i.e., Gerhard Liepold and Dietrich Bizer, are the same in both in the Liepold reference and the present application. Furthermore, the assignee, i.e., GL Tool and Manufacturing Co. Inc, are the same in both Liepold reference (see attached PCT/IB/306, PCT Notification of the Recording of a Change, Dated October 21, 2004 for PCT/US2003/012924, copy attached) and the present application (see attached copy of the assignment recordation abstracts for the present application). Therefore Liepold does not to qualify as prior art under 35 U.S.C. Section 102 (e). It is noted that at paragraph 8 of the Office Action the Examiner states that it is presumed that the

claims of the present application were commonly owned at the time the inventions covered therein were made in the absence of any evidence to the contrary. Applicants did not submit any evidence to the contrary. Yet, at paragraph 10 of the Office Action, the Examiner appears to use the Liepold reference as a prior art qualifying under Section 102(e), i.e. an application *by another* filed before the invention the invention be the applicant for patent. The prior art patent application Liepold was not filed by *another* within the meaning of Section 102(e) and therefore does not qualify as prior art under Section 102(e). The Liepold prior art patent application claims a priority date of 26th April 2002 which is earlier than the priority date of 3rd August 2003 of amended Claim 50. However, Liepold was published on 6th November 2003 which is after the priority date of amended Claim 50. Thus, the Liepold reference does not qualify under Section 102 (a) or (b) or (d) either. Sections 102 (c), (f) or (g) are not applicable at all.

Thus, Liepold should not be considered as a prior art reference.

Assuming *arguendo* that Liepold is valid prior art, for the sake of completeness however, in response to the Examiner's opinion at paragraph 10 of the Office Action that Claim 50 is obvious over Liepold in view of Rovira, Applicants respectfully disagree. Contrary to the Examiner's view expressed at paragraph bridging pages 16 and 17, Rovira does not disclose the feature of amended Claim 50

“wherein in the closed position of the valve (1, 121, 700, 800, 400, 900, 990), the sharp rim (15) is engaged with the curved surface area (22) and a portion of the curved surface area (22) is displaced by the sharp rim (15) and wherein the materials of the sharp rim (15) and the curved surface area (22) are elastically deformed to seal the opening of the valve (1, 121, 700, 800, 400, 900, 990)”

In several places throughout the Rovira reference it is stated only a line contact is enabled between the closure member 3 and the valve seat 4, see last sentence of each of [0005], [0006], [0009], [0038], [0042], [0043] and [0045]. There is no disclosure of the displacement of material between the two plastic portions as provided for in the amended Claim 50. Moreover,

Rovira aims at reducing the actuating force for actuating the valve, see [0012], and accordingly the force between the closure member 3 and the valve seat 4.

For the above reasons it is submitted that amended Claim 50 is novel and not obvious having regard to the prior art cited in the Office Action. With regard to dependent Claims 59 to 65, these claims are patentable because they depend upon independent Claim 50, which is new and involves an inventive step for the reasons given above.

Reconsideration and withdrawal of the rejections of Claims 50 and 59-65 under 35 U.S.C. §103(a) are respectfully requested.

C.) In paragraph 11 of the Office Action, claim 67 is rejected under 35 U.S.C. §103(a) as allegedly being obvious over Liepold in view of Rovira further in view of US 1,387,446 to Astier (hereinafter “Astier”). Applicants respectfully traverse.

Astier is cited by the Examiner for certain alleged teachings regarding seals and seal displacement means. Assuming *arguendo* that Liepold is valid prior art, it is respectfully submitted, however, that Astier fails to cure the deficiencies of Liepold. Reconsideration and withdrawal of the rejections of claims 67 under 35 U.S.C. §103(a) is respectfully requested.

Summary

Therefore, Applicants respectfully submit that claims 50-54 and 56-67 are patentably distinct. This application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited, including rejoinder and allowance of the withdrawn claims 68-90.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if any, under 37 C.F.R. § 1.17 and also should be treated as a constructive petition for an extension of time in this reply or any future reply pursuant to 37 C.F.R. § 1.136.

Respectfully submitted,

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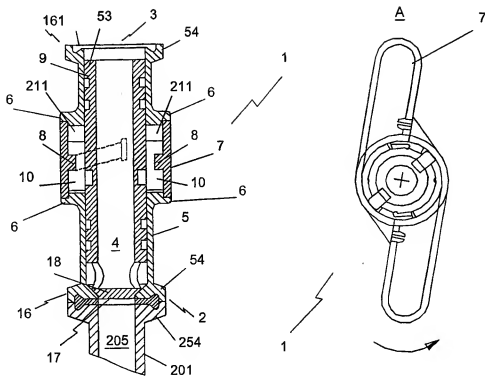
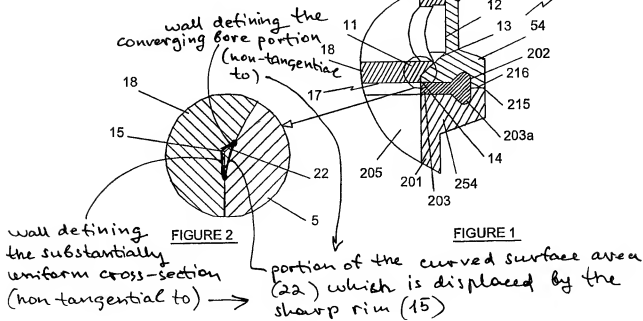


FIGURE 4

FIGURE 3



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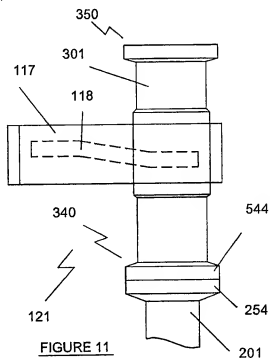
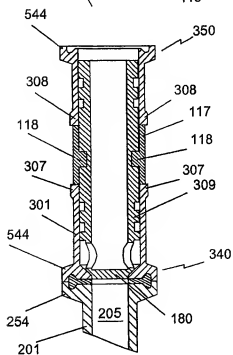
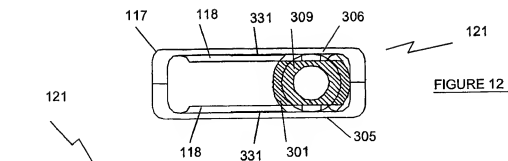
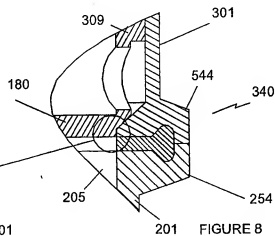
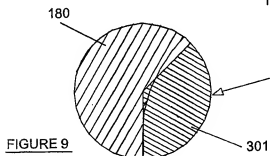


FIGURE 10

FIGURE 11



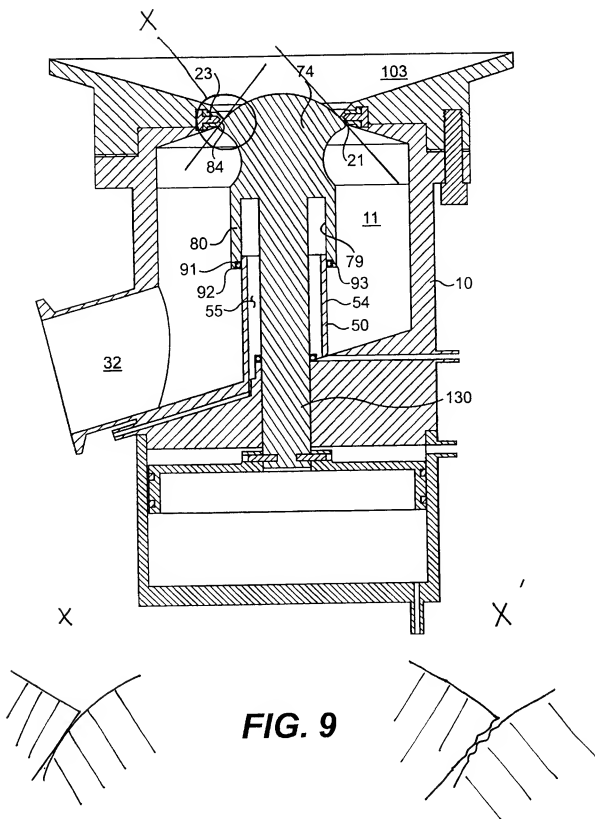
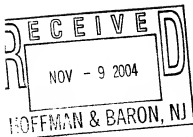


FIG. 8

PATENT COOPERATION TREATY



PCT

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
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From the INTERNATIONAL BUREAU

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SCOLA, Daniel, A., Jr.
Hoffmann & Baron, LLP
6900 Jericho Turnpike
Syosset, NY 11791
United States of America

NOV - 3 2004

Date of mailing (day/month/year) 21 October 2004 (21.10.2004)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 1350-2 PCT	
International application No. PCT/US2003/012924	International filing date (day/month/year) 25 April 2003 (25.04.2003)

1. The following indications appeared on record concerning:

☒ the applicant ☐ the inventor ☐ the agent ☐ the common representative

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State of Nationality

IE

State of Residence

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Telephone No.

Facsimile No.

Teleprinter No.

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☒ the person ☐ the name ☐ the address ☐ the nationality ☐ the residence

Name and Address

GL TOOL AND MANUFACTURING CO. INC.
26 Okner Parkway
Livingston, NJ 07039
United States of America
(Applicant for all designated States except US)

State of Nationality

US

State of Residence

US

Telephone No.

Facsimile No.

Teleprinter No.

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

☒ the receiving Office ☐ the designated Offices concerned
☐ the International Searching Authority ☒ the elected Offices concerned
☒ the International Preliminary Examining Authority ☒ other: G.A. APOLLO LIMITED ;

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1211 Geneva 20, Switzerland

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Patent #: NONE	Issue Dt:	Application #: 10566611	Filing Dt: 01/31/2006
Publication #: 20060243942	Pub Dt: 11/02/2006	PCT #: US0424732	
Inventors: Gerhard Liepold, Dietrich Bizer			
Title: Valve			

Assignment: 1

Reel/Frame: 015677/0198	Recorded: 07/30/2004	Pages: 3
Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).		
Assignor: <u>BIZER, DIETRICH</u>	Exec Dt: 07/30/2004	
Assignee: GL TOOL & MANUFACTURING CO. INC. 26 OKNER PARKWAY LIVINGSTON, NEW JERSEY 07039		
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Assignment: 2

Reel/Frame: 015657/0954	Recorded: 02/04/2005	Pages: 5
Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).		
Assignor: LIEPOLD, GERHARD	Exec Dt: 02/01/2005	
Assignee: GL TOOL AND MANUFACTURING CO. INC. 26 OKNER PARKWAY LIVINGSTON, NEW JERSEY 07039		
Correspondent: HOFFMANN & BARON, LLP JOHN S. SCOLA, JR. 6900 JERICHO TURNPIKE SYOSSET, NY 11791		

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